ATTACHMENT 16

Case 3:21-cv-03496-AMO Document 229-16 Filed 05/17/24 Page 2 of 16

Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 1 of 15 PageID 36852

UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

REBOTIX REPAIR, LLC,

Plaintiff / Counterclaim Defendant,

V.

Case No. 8:20-cv-2274-VMC-TGW

INTUITIVE SURGICAL, INC.,

FILED UNDER SEAL

Defendant / Counterclaim Plaintiff.

SEALED ORDER

This matter comes before the Court upon consideration of Defendant Intuitive Surgical, Inc.'s Sealed <u>Daubert</u> Motion to Exclude the Opinions of Gwen Mandel and Kurt Humphrey. (Doc. # 105). Plaintiff Rebotix Repair, LLC has responded, and Intuitive replied. (Doc. ## 131, 140). For the reasons that follow, the Motion is denied.

I. Background

The Court and the parties are well familiar with the background facts and claims in this case, and the Court will not belabor them here. Suffice it to say that this is an antitrust suit initiated by Rebotix, a company that offers a service whereby it "repairs" the EndoWrist surgical implement originally manufactured by Intuitive.

Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 2 of 15 PageID 36853

While it is undisputed that Rebotix can reset the usage counter on the da Vinci S and Si EndoWrist models, the parties hotly contest the viability of Rebotix being able to similarly "repair" the newer versions of the EndoWrist, the X and Xi models. As it explains, Rebotix retained Gwen Mandel and Kurt Humphrey "to demonstrate the feasibility of Rebotix's repairs of . . X/Xi EndoWrists" and to "offer opinions on the feasibility of completing the X/Xi workaround."

Gwen Mandel is a cybersecurity consultant with a Master's degree in Physics with an emphasis on medical physics. (Doc. # 105-2 at 1). She has ten years' experience with medical software, coding, and programming. Mandel explained that on the da Vinci Xi model, the usage counter is located on an RFID computer chip. (Id. at 2). Mandel analyzed the RFID computer chip taken from an EndoWrist Xi instrument and drew three conclusions: (1) the chip does not have any cybersecurity that would prevent writing data onto the chip; (2) the methodology that Mandel used allowed her to establish two-way communication with the chip, and she can extract a

 $^{^1}$ The S- and Si-generation EndoWrists operate via a hardwire connection, whereas the X- and Xi-generation EndoWrists operate on a radio frequency identification (RFID) system. (Doc. # 114-2 at 14).

full unencrypted image from the chip; and (3) writing data to the chip is a "straightforward" process. (Id. at 13-14).

Kurt Humphrey is the managing director and principal technologist at IP Enginuity, LLC. (Doc. # 105-4 at 1). He has more than 20 years' experience with integrated circuit Не and smart sensor processing. has reversedevices engineered a large number of semiconductor devices, including microprocessors. Humphrey also formed three opinions in this case. First, it is a "simple process" to extract images from the computer chip embedded in the EndoWrist X/Xi models and there are two possible ways to do so - the RFID method and the "direct hardwire extraction method." (Id. at 15). Second, Rebotix will be able to identify the usage counter in the extracted image. (Id. at 15-16). Third, Rebotix will have the capability to implement a reset of the usage counter on the X/Xi EndoWrists. (Id. at 16). "After image extraction, the process of resetting the usage counter on the X/Xi EndoWrists will be easier than resetting the usage counter on the S/Si EndoWrists due to the reprogrammable nature" of the chip. (Id.).

Now, Intuitive seeks to exclude the testimony of Mandel and Humphrey. Rebotix has responded, and the Motion is ripe for review.

Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 4 of 15 PageID 36855

II. Discussion

Federal Rule of Evidence 702 states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Implementing Rule 702, <u>Daubert v. Merrell Dow Pharms.</u>, <u>Inc.</u>, 509 U.S. 579 (1993), requires district courts to ensure that any and all scientific testimony or evidence admitted is both relevant and reliable. <u>See Id.</u> at 589-90. The <u>Daubert analysis also applies to non-scientific expert testimony. <u>Kumho Tire Co. v. Carmichael</u>, 526 U.S. 137, 147 (1999). District courts must conduct this gatekeeping function "to ensure that speculative, unreliable expert testimony does not reach the jury under the mantle of reliability that accompanies the appellation 'expert testimony.'" <u>Rink v.</u> Cheminova, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005).</u>

The Eleventh Circuit "requires trial courts acting as gatekeepers to engage in a 'rigorous three-part inquiry.'"

Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 5 of 15 PageID 36856

Hendrix v. Evenflo Co., 609 F.3d 1183, 1194 (11th Cir. 2010).

The district court must assess whether:

(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

<u>Id.</u> The proponent of the expert testimony bears the burden of showing, by a preponderance of the evidence, that the testimony satisfies each of these requirements. Id.

Intuitive does not attack the qualifications of Mandel and Humphrey, but instead argues that their methodologies are unreliable and that their opinions will not assist the trier of fact because they are speculative and irrelevant.

1. Reliability

"Exactly how reliability is evaluated may vary from case to case, but what remains constant is the requirement that the trial judge evaluate the reliability of the testimony before allowing its admission at trial." United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004) (citing Fed. R. Evid. 702, Advisory Committee Notes (2000)). There are four recognized, yet non-exhaustive, factors a district court may consider in evaluating reliability:

Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 6 of 15 PageID 36857

(1) whether the expert's methodology has been tested or is capable of being tested; (2) whether the technique has been subjected to peer review and publication; (3) the known and potential error rate of the methodology; and (4) whether the technique has been generally accepted in the proper scientific community.

Seamon v. Remington Arms Co., 813 F.3d 983, 988 (11th Cir. 2016) (citations omitted). A district court can take other relevant factors into account as well. Id. (citations omitted).

"If the [expert] witness is relying solely or primarily on experience, then," in establishing reliability, "the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Frazier, 387 F.3d at 1261 (citation and internal quotation marks omitted). The Court's analysis as to reliability "focus[es] 'solely on principles and methodology, not on the conclusions that they generate.'" Seamon, 813 F.3d at 988 (citation omitted).

Intuitive argues that Mandel and Humphrey's opinions are unreliable for three reasons.

a. Mandel's methodology

Mandel wrote the following in her report:

Case 3:21-cv-03496-AMO Document 229-16 Filed 05/17/24 Page 8 of 16

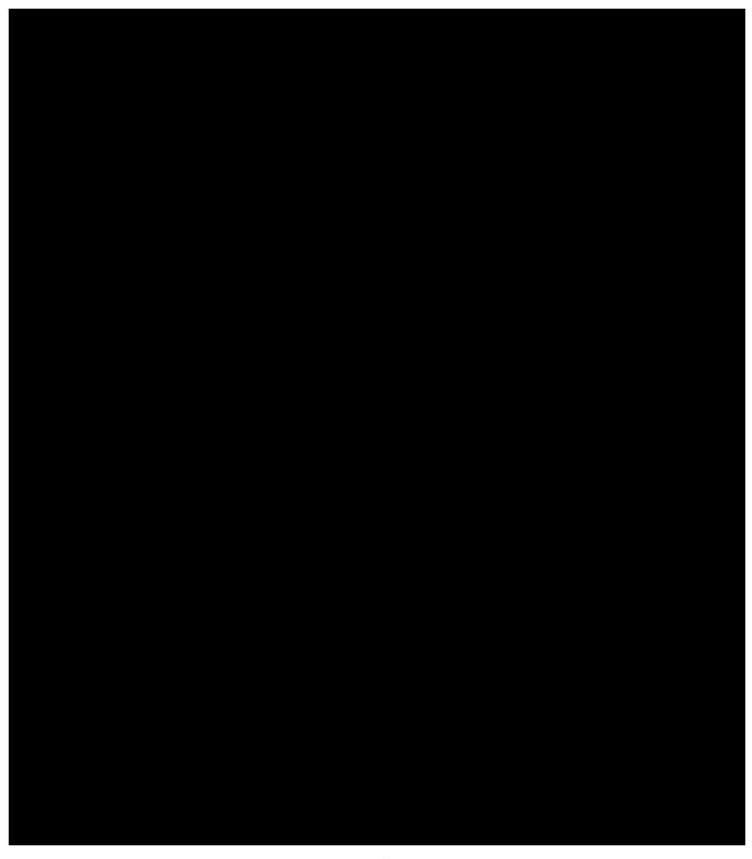
Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 7 of 15 PageID 36858

Case 3:21-cv-03496-AMO Document 229-16 Filed 05/17/24 Page 9 of 16

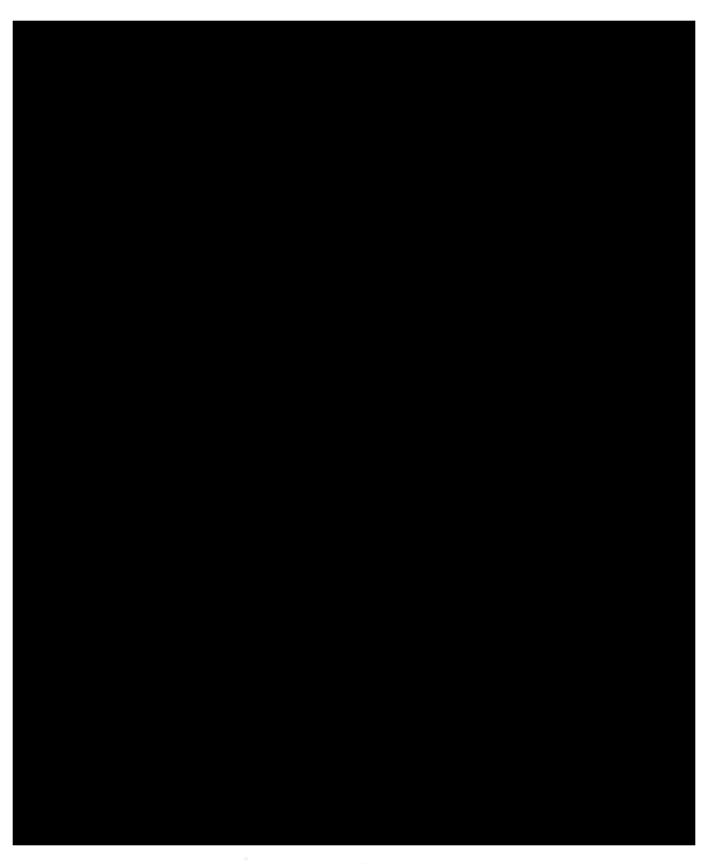


Case 3:21-cv-03496-AMO Document 229-16 Filed 05/17/24 Page 10 of 16

Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 9 of 15 PageID 36860



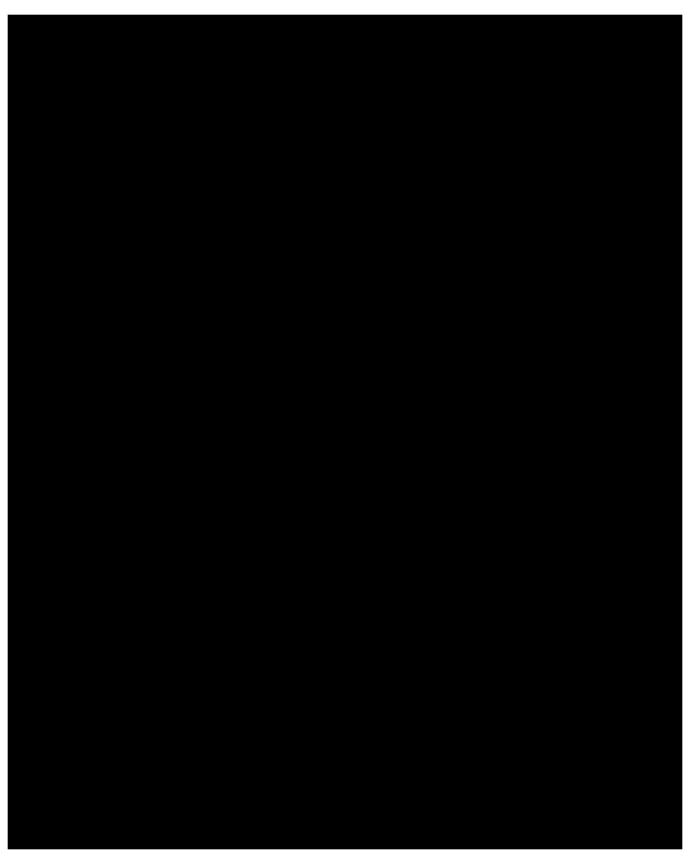
Case 3:21-cv-03496-AMO Document 229-16 Filed 05/17/24 Page 11 of 16



Case 3:21-cv-03496-AMO Document 229-16 Filed 05/17/24 Page 12 of 16



Case 3:21-cv-03496-AMO Document 229-16 Filed 05/17/24 Page 13 of 16



Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 13 of 15 PageID 36864

2. Assistance to Trier of Fact

Expert testimony must also assist the trier of fact. Fed. R. Evid. 702. "By this requirement, expert testimony is admissible if it concerns matters that are beyond the understanding of the average lay person." Frazier, 387 F.3d at 1262 (citation omitted). "[T]he court must 'ensure that the proposed expert testimony is "relevant to the task at hand," . . . i.e., that it logically advances a material aspect of the proposing party's case.'" Allison v. McGhan, 184 F.3d 1300, 1312 (11th Cir. 1999).

So, while "[t]he 'basic standard of relevance . . . is a liberal one,' <u>Daubert</u>, 509 U.S. at 587, . . . [,] if an expert opinion does not have a 'valid scientific connection to the pertinent inquiry[,]' it should be excluded because there is no 'fit.'" <u>Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.</u>, 582 F.3d 1227, 1232 (11th Cir. 2009) (citations omitted). "Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments." Frazier, 387 F.3d at 1262-63 (citation omitted).

Here, it is undisputed that Rebotix has never been able to successfully override the use limits on X and Xi EndoWrists. Intuitive argues that "Rebotix is claiming the

right to antitrust damages regarding these [X/Xi] instruments based on the unproven assumptions of its experts [Mandel and Humphrey]." (Doc. # 105 at 7). According to Intuitive, because Rebotix hasn't been able to actually override the use counter on the X/Xi models, it cannot show "preparedness to enter the market," a requirement for antitrust standing. (Id. at 7-9).

The Court agrees with Rebotix that Mandel and Humphrey's opinions will help the trier of fact understand a complex and highly technical subject and, moreover, are not irrelevant. As the Court explained in its summary judgment order, Rebotix claims that further development of an override of the X/Xi EndoWrist was futile in light of Intuitive's anti-competitive conduct, and there is sufficient evidence to allow this issue to proceed to a jury. See Sanger Ins. Agency v. HUB Int'l, Ltd., 802 F.3d 732, 740 (5th Cir. 2015) ("The degree to which a business must take affirmative steps is mitigated by the impact of the antitrust violation, which we assume to have occurred when analyzing standing. Thus nascent competitors need not pay a courtroom entrance fee in the form of an substantial resources expenditure of clearly futile competitive gesture.").

Case 3:21-cv-03496-AMO Document 229-16 Filed 05/17/24 Page 16 of 16

Case 8:20-cv-02274-VMC-TGW Document 188 *SEALED* (Court only) Filed 08/10/22 Page 15 of 15 PageID 36866

Accordingly, it is hereby

ORDERED, **ADJUDGED**, and **DECREED**:

Defendant Intuitive Surgical, Inc.'s Sealed <u>Daubert</u>
Motion to Exclude the Opinions of Gwen Mandel and Kurt
Humphrey (Doc. # 105) is **DENIED**. The Clerk is directed to
mail a copy of this Order to counsel for the parties.

DONE and ORDERED in Chambers in Tampa, Florida, this 10th day of August, 2022.

VIRGINIA M. HERNANDEZ COVINGTON UNITED STATES DISTRICT JUDGE